

Applicants' apparatus provides, a treatment for undesirable bleeding, associated with various medical disorders for example uterine bleeding. Conventional medical procedures for treating such bleeding involve surgical removal of living endometrial tissue with the attendant patient stress and risks. A more modern procedure involves burning away endometrial tissue with a laser device. This latter procedure reduces patient stress but requires a very high level of skill to perform safely. Perforation of a patients' uterus by the laser could cause death.

Applicants' have invented an apparatus that is intended to effect necrosis of the tissue lining a body cavity without the hazards and disadvantages associated with the described conventional surgical and laser surgical procedures.

Claims 1 to 3, 8 to 12, 18, 20 and 25 stand rejected under 35 U.S.C. § 103 as obvious over Doering in view of Ginsburg et al. and Bonnet et al. The new primary reference Doering (Patentschrift No. 895,046) is relied on as disclosing

"An apparatus for heating the uterine endometrium for disease treatment as claimed by applicant, except that there is no mention of effecting necrosis of the tissue and there is no one control means for inflating and heating the bladder."

It should be recognized at the outset that, the disease treatment contemplated by Doering involves gently warming of internal organs with a heated fluid-filled bladder to produce hyperemia. This is entirely different from the treatment provided by Applicants' apparatus which kills tissue contacting the heated bladder. The structural differences in the Doering apparatus and Applicants' device are a consequence of the different purposes for which they are used.

In other words, an important purpose of Doering in designing his apparatus was to avoid tissue damage which is in

complete conflict with Applicants' purpose of necrosing tissue. Given these conflicting purposes, Doering cannot be properly combined with the secondary references for teaching or suggesting anything about making a device for necrosing tissue. At the top of page 2 of the translation Doering contrasts his device with conventional diathermy electrodes noting the danger of overdosing and burning, and that self-treatment with such devices is impossible.

Clearly, it is only with the benefit of Applicants' disclosure of why and how an apparatus for necrosing tissue should be made that the Examiner can focus on Doering's teachings to suggest an apparatus intended to avoid burning tissue. In retrospect the differences between Applicants' apparatus and that of Doering, may seem simple and small to the Examiner; but the proper perspective for evaluating Doering's teachings is what one of ordinary skill in the art could have learned from them. From that perspective Doering would not have taught anything useful in making Applicants' invention. It should not be overlooked when considering the question of obviousness in this case that the medical establishment has moved toward complicated and expensive laser technology to necrose body cavity lining (uterine). If a simple and inexpensive heated balloon was an obvious approach, why didn't someone do it before, especially when one further considers that Doering has been available since 1953.

The Ginsburg et al. reference, adds nothing meaningful to the teaching's of Doering. As pointed out in Applicants' previous remarks, which are hereby repeated and incorporated herein by reference, the Ginsburg et al. disclosure is directed to a balloon-tipped catheter including means for heating a fluid within the balloon to promote restoration and healing of an arterial wall in the region of a

stenosis. Ginsburg et al., like Doering, has nothing to do with necrosing tissue in a body cavity. Where is the required suggestion to modify the teaching of Doering with those of Ginsburg et al. as proposed by the Examiner? There simply is none; because both of these references are aimed at an entirely different purpose.

The Bonnet et al. reference is directed to an instrument for endoscopic operations. The passage at col. 4, lines 46 to 56 cited by the Examiner is only an incidental disclosure and describes a procedure for closing the cystic duct by coagulation of gall bladder tissue and necrosis of gall bladder mucous membrane, that may involve introducing either a fluid at a predetermined temperature or a "thermoprobe" through a trocar sleever insert. One skilled in the art wishing to necrose the tissue lining of a body cavity and following this teaching would, at most, be led to simply introduce hot fluid or a hot instrument to that body cavity. That approach would neither produce the same results as Applicants' apparatus nor does it suggest Applicants' apparatus. In fact, it is doubtful that the procedure described by Bonnet et al. would be reliable and effective for its stated purpose, other than in highly localized applications because, as a practical matter, only relatively small amounts of heat (hot fluid) could be delivered to a body cavity as described. Large volumes of hot fluid would be difficult to handle and very dangerous to surrounding tissue.

Guidance for properly making obviousness determinations in this type of case is found in In re Randall J. Wright, 6 U.S.P.Q. 1959 (Fed. Cir. 1988) (copy enclosed for Examiner's convenience). In Wright the Federal Circuit reversed the Board's affirmance of the Examiner's final rejection under 35 U.S.C. § 103. Wright's invention was a carpenter's level-

measuring instrument having a liquid filled, transparent vial which narrowed toward its opposing ends, i.e., a barrel-shape, and a core pin disposed in the vial so that the indicator bubble does not move as far along the barrel with a given change of pitch. The Board held that it would have been obvious to combine the prior art teachings of a barrel shaped level vial (Vaida) with a cylindrical level vial including a core pin used to increase visibility of the indicator bubble.

The Federal Circuit reversed the Board's prima facie obviousness holding because an invention must be considered as a whole (i.e., structure, its properties, and the problem it solves) when making obviousness determinations under 35 U.S.C. § 103.

The Wright invention was directed to improving pitch-measurement -- not bubble visibility! None of the references relied on by the Board taught or suggested the improved pitch measurement achieved by Wright's claimed structure. Therefore, the Wright invention was held not prima facie obvious.

Similarly, the prior art in this case will not support the rejections because neither Doering nor Ginsburg et al. have anything to do with necrosing tissue. In fact, a goal of Doering's device is to avoid tissue necrosis. Bonnet et al. is directed to an endoscopic device and teaches nothing more than that body tissue can be necrosed by hot fluid.

Claims 6 and 7, 13 to 17, 19 and 26 are rejected over the combination of Doering, Ginsberg et al. and Bonnet et al. as discussed above taken further in view of either Landman et al., Solar, Solar and Wood or Moore et al.

None of these rejections are supported by the prior art due to the deficiencies in the primary combination of

Doering, Ginsburg et al. described above and they should be withdrawn.

Landman et al. - disclose hypodermic syringe and three-way valve for inflating and deflating catheters particularly for use in the blood carrying arteries and veins and has nothing to do with necrosis of tissue.

Solar - is directed to a balloon catheter for assisting right ventricle (heart) function and has absolutely nothing to do with necrosis of tissue.

Wood - discloses an apparatus for applying dry heat to the body including an expandible container 32 having a heating element disposed therein but discloses nothing about necrosis of tissue.

Moore et al. - disclose an endoscope having scale gradations thereon but discloses nothing about necrosis tissue.

Finally, the Examiner's attention is respectfully directed to the Ott reference which was not relied on to support any rejection and Applicants' reserve the right to swear behind. This reference, based on a patent application filed in 1987, should be reviewed carefully because it is actually evidence of unobviousness. It surely wasn't obvious to Mr. Ott that he could perform the described surgical procedure with a heated balloon.

None of the cited references teach or suggest anything about constructing a catheter apparatus for the purpose of necrosing tissue; thus, the references taken alone or in any combination will not support the rejection.

Applicants believe that this application is now in condition for allowance and such action is respectfully requested. If the Examiner believes that the prosecution of this case could be advanced by contact with Applicants'

attorney he is invited to contact the undersigned at the number given below.

Respectfully submitted,

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